IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION

BECKY J. WRIGHT, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 06-CV-4183-NKL
	)	
AMERICAN HOME PRODUCTS CORPORATION, et al.	)	
	)	
Defendants.	)	

ORDER

This case involves alleged injuries suffered by Plaintiff Becky Wright as a result of ingesting fenfluramine, marketed as Pondimin, by its manufacturer(s) and/or marketer(s): American Home Products Corporation, Wyeth, Inc., and Wyeth-Ayerst International, Inc.[1] Pending before the Court are Plaintiffs' Motion for Summary Judgment on two of Defendants' affirmative defenses [Doc. # 43]. For the reasons stated herein, Plaintiffs' Motion is denied.

I. Background

Plaintiff Becky J. Wright ("Wright") filed this product liability action to recover damages for injuries she allegedly sustained from using fenfluramine ("Pondimin"), a prescription diet drug. Her husband, Ernest, brings suit for loss of consortium as a result of Wright's injuries. Wright suffers from a fatal disease called Primary Pulmonary

[1] When fenfluramine was prescribed in combination with the drug phentermine, these weight-loss drugs were popularly known, advertised, promoted and referred to as "phen-fen" or "fen/phen."

Hypertension ("PPH") for which there is no cure. Wright alleges that her PPH was induced by ingesting Pondimin. Wright alleges the following claims against Wyeth: (1) negligence and negligence per se; (2) design and marketing defect; (3) failure to warn; (4) misrepresentation and fraudulent misrepresentation; (5) strict product liability; and, (6) breach of implied warranty of merchantability. Wright's claims are similar to those asserted in other actions filed by plaintiffs across the country claiming damages allegedly resulting from the manufacture and sale of Pondimin and dexfenfluramine ("Redux") (collectively "the diet drugs").[2] Defendants American Home Products Corporation, Wyeth, Inc., and Wyeth-Ayerst International, Inc. (collectively "Wyeth"), manufactured and distributed the diet drugs. Wyeth withdrew the diet drugs from the world market on September 15, 1997.

Wright's physician, Dr. David Scott, prescribed Pondimin to Wright in April, 1996. The parties dispute the knowledge available to Dr. Scott and Wyeth before he prescribed Pondimin to Wright. The 1996 Physician's Desk Reference Pondimin label noted that:

> There have been four cases of pulmonary hypertension reported in association with fenfluramine use. Two cases were apparently reversible after discontinuation of fenfluramine, but evidence of pulmonary hypertension recurred in one of these patients upon rechallenge with fenfluramine. A third patient was initially improved with nifedipine treatment, but was noted to have increased pulmonary arterial pressure against at a four month follow up visit. Finally, an irreversible and fatal case of pulmonary hypertension has been reported in a patient who had seven 1-month courses of fenfluramine in the twelve years prior to death. Patients

[2] Pondimin is Wyeth's trade name for the drug fenfluramine. Redux is Wyeth's trade name for the drug dexfenfluramine.

> taking fenfluramine should be advised to report immediately any deterioration in exercise tolerance. (Physician's Desk Reference 2066 (1996)).

In 1994, when the FDA approved the Pondimin label listing four cases of pulmonary hypertension, Wyeth knew of at least 37 reports of pulmonary hypertension in association with Pondimin. In 1994 Wyeth also knew of 74 cases of pulmonary hypertension in association with Redux.

In addition to PPH, Wright claims that Wyeth knew of signals that Pondimin use caused valvular heart disease; i.e., any disease involving one or more valves of the heart, which would have caused Dr. Scott not to prescribe Pondimin to her.[3] In 1991, Wyeth received a Pondimin adverse drug event ("ADE") report that included valvular heart disease ("aortic insufficiency 2/4 is a report of valvular heart disease.").[4] As of April 19, 1994, Wyeth had received four ADEs containing the terms "aortic insufficiency," "mitral insufficiency," "aortic failure" or "mitral failure." Wyeth disputes that these are necessarily "diseases." On January 5, 1996, Wyeth received six ADEs for cardiovascular disorder containing the terms "aortic insufficiency," "mitral regurgitation" or "AI" and reported none of them to the FDA prior to March 1997. On a single day in January 5, 1995, Wyeth received at least thirteen follow-up or initial ADE reports which contained indications of aortic and/or mitral regurgitation. (Doc. 46 Ex. 18B, 9). Dr. Scott

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[3] The "aortic" and "mitral" valves on the left of the heart and the "pulmonary" and "tricuspid" valves on the right. *See Lachance v. American Home Products Corp*., 2006 U.S. Dist. LEXIS 1153 (W.D. Mo. 2006).

[4] Wyeth states in response that "aortic regurgitation" is not necessarily the same as valvular heart disease. (Doc. 46 Ex. 9).

concludes that had he known about "either the risks of valvular heart disease or all of the reported cases of pulmonary hypertension . . . that Wyeth was aware of, I would have concluded that the risks of Pondimin outweighed any possible benefit to Becky Wright and I would not have prescribed Pondimin to her." (Scott Aff. ¶ 8).

Wyeth claims that it was "in compliance with the labeling requirement with both Redux and Pondimin." (Feigal Report, 5). Wyeth also denies that the risk of heart valve regurgitation was not reasonably known to it during 1994, 1995 and 1996 "based on the information available to it." (Arrowsmith-Lowe Report, 11-12). Wyeth also asserts that Dr. Scott had independent knowledge of the risks that allegedly should have been communicated. For example, Dr. Scott was aware of the risk of pulmonary hypertension associated with Redux. (Scott Dep., 139).

II. Discussion

Summary judgment is proper if the evidence, viewed in the light most favorable to the nonmoving party, indicates there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *Castillo v. Ridge*, 445 F.3d 1057, 1060 (8th Cir. 2006), citing *Gipson v. Immigration and Naturalization Service*, 284 F.3d 913, 916 (8th Cir. 2002). The summary judgment rule is intended "to isolate and dispose of factually unsupported claims" and should be applied to accomplish this purpose. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-324 (1986). When a party moving for summary judgment points out an absence of evidence on a dispositive issue for which the non-moving party bears the burden of proof at trial, the non-moving party must "go beyond

the pleadings and by [his] own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 324-25 (1986) (internal quotations and citation omitted). Thereafter, summary judgment is mandated against the non-moving party who fails to make a showing sufficient to establish a genuine issue of fact for trial. *Id*. at 322, 324-25. The party opposing a motion for summary judgment must rely on more than conclusory statements or allegations unsupported by facts. *Davis v. U.S. Bancorp,* 383 F.3d 761, 765 (8th Cir. 2004) (citation omitted). The Court must consider all inferences drawn from the underlying facts in a light most favorable to the party opposing the motion, and resolve all reasonable doubts against the moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Summary judgment is not proper if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Anderson*, 477 U.S. at 248.

A. Comment (k) to Section 402A of the Restatement (Second) of Torts

Under Missouri law, drug manufacturers are provided an exception to strict liability for some "unavoidably unsafe products" such as experimental drugs. In order to receive protection under Comment (k), the manufacturer must show (1) the drug's risk is unavoidable and (2) the overall benefit of the drug outweighs the risk created by it. *Pollard v. Ashby*, 793 S.W.2d 394, 398-99 (Mo. Ct. App. 1990). The first element is proved by demonstrating that, given the current state of knowledge, no feasible alternative design exists that would accomplish the same purpose with a lesser risk. The

second element is necessarily fact-intensive as "it does not serve society that an unavoidably unsafe product, which has occasional or fractious benefit should enjoy insulation from strict liability in tort when the product's predominant effects are detrimental to individual and public safety." *Id.* at 400.

Wyeth asserts two arguments as to the first element of the Comment (k) affirmative defense: (1) that phentermine, for which no epidemiological study has shown enhanced risk of PPH or valvular heart disease, is a *substitute*, as opposed to an *alternative design* and (2) Pondimin and phentermine were prescribed together to offset their combined side effects thus they are "complementary products."

The Eastern and Western Districts of Missouri have already concluded that the application of Comment (k) to Pondimin is a question of fact for the jury. *Hill v. Wyeth, Inc.*, 2007 U.S. Dist. LEXIS 13596 (E.D. Mo. 2007) (citing *Lachance v. American Home Products Corp*., 2006 U.S. Dist. LEXIS 1153 (W.D. Mo. 2006)).[5] This Court concurs.

B. Learned Intermediary Defense

Wyeth alternatively pleads the learned intermediary affirmative defense to bar Wright's claims. This doctrine provides that a pharmaceutical manufacturer has a duty to warn a physician of the risks involved with a pharmaceutical, and the physician then acts as a "learned intermediary" between the manufacturer and the physician's patient.

Wyeth's statement that "FDA-approved labeling for phentermine today includes warnings about both PPH and heart valve disease" raises a narrow, if sufficient, basis to deny summary judgment. The warning for phentermine states that PPH has been reported in patients taking both fenfluramine and phentermine and that PPH or valvular heart disease "cannot be ruled out" as a result of using phentermine alone. There is no epidemiological study that purports to show that phentermine causes either PPH or valvular heart disease. (Doc. 46, 11).

Lachance v. American Home Products Corp., 2006 U.S. Dist. LEXIS 1153 (W.D. Mo. 2006) (citing *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016 (8th Cir. 2004)). "A warning to the [physician] is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of prescription drugs." *Id*. (quoting *Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 671 (8th Cir.1985)). The failure of a drug manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is "not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warnings should have communicated." *Id*. (citing *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 419-420 (Mo. 1999)).

In this case, there are genuine issues of material fact as to whether Dr. Scott had independent knowledge of the risks the adequate warnings should have communicated. Dr. Scott prescribed Redux after knowing about a significant warning identifying 95 PPH cases related to Redux. (Scott Dep., 85, 139). Moreover, Wyeth sent "Dear Doctor Letters" to physicians warning of the PPH risks associated with Pondimin. Although Dr. Scott does not recall receiving such a letter, his name appears on a list of physicians to whom the letters were sent. There is thus a material issue of fact as to whether the learned intermediary affirmative defense applies.

III. Conclusion

Accordingly, it is hereby

ORDERED that Plaintiffs' Motion for Summary Judgment [Doc. # 43] is DENIED.

s/ NANETTE K. LAUGHREY
NANETTE K. LAUGHREY
United States District Judge

Dated: April 18, 2008
Jefferson City, Missouri